UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LINDA EVANGELISTA, *Plaintiff,* -against- ZELTIQ AESTHETICS, INC., *Defendant.*	**CASE NO: 21-cv-7889** **PLAINTIFF LINDA EVANGELISTA'S OPPOSITION TO DEFENDANT ZELTIQ AESTHETIC, INC.'S MOTION TO DISMISS**

WROBEL MARKHAM LLP

1407 Broadway, Suite 4002
New York, NY 10018
Tel: (212) 421-8100
Fax: (212) 421-8170
Attorneys for Plaintiff Linda Evangelista

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

RULES

INTRODUCTION

In its motion to dismiss the Amended Complaint in part, defendant Zeltiq Aesthetics, Inc. ("Zeltiq") takes several passes at avoiding liability on plaintiff Linda Evangelista's claims for strict liability (Counts I-II), negligence (Count III), breach of warranty (Counts IV-V), fraud (Counts VI-IX), and violations of N.Y. GBL §§ 349 and 350. Zeltiq asks the Court to dismiss these claims as time-barred, despite acknowledging (in a footnote) that the parties executed a series of tolling agreements while they attempted to negotiate a resolution and even participated in mediation in April 2020. Zeltiq's argument that Counts I-X are time-barred is not only disingenuous but rebutted by a simple amendment to the Amended Complaint. Zeltiq also seeks to escape liability by way of the learned intermediary doctrine but fails to either show that the doctrine applies in this instance or establish that its warnings were adequate as a matter of law. Zeltiq even challenges the sufficiency of Ms. Evangelista's claims for breach of express warranty (Count IV), fraud (Counts VI-IX) and violations of N.Y. GBL §§ 349 and 350 (Count X), but ignores the pleaded facts which, accepted as true, sufficiently state claims for each cause of action.

ARGUMENT

I. Legal Standard

"To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must allege sufficient facts, taken as true, to state a plausible claim for relief." *Johnson v. Priceline.com, Inc.*, 711 F.3d 271, 275 (2d Cir. 2013)(citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007)). "[A] complaint does not need to contain detailed or elaborate factual allegations, but only allegations sufficient to raise an entitlement to relief above the speculative level." *Keiler v. Harlequin Enters., Ltd.*, 751 F.3d 64, 70 (2d Cir. 2014). In deciding the motion, courts must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's

favor." *L.C. v. LeFrak Org., Inc.*, 987 F.Supp.2d 391, 398 (S.D.N.Y. 2013)(quoting *LaFaro v. N.Y. Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009)). "Dismissal is inappropriate unless it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief." *Id.* (quoting *Sweet v. Sheahan,* 235 F.3d 80, 83 (2d Cir. 2000)). Moreover, when a motion to dismiss is granted, "'[i]t is the usual practice ... to allow leave to replead.'" *Schindler v. French,* 232 Fed.Appx. 17, 19 (2d Cir. 2007)(quoting *Cortec Indus., Inc. v. Sum Holding L.P.,* 949 F.2d 42, 48 (2d Cir.1991)).

II. Plaintiff's Claims Are Not Time-Barred.

Zeltiq's request that this Court dismiss Counts I-X as time-barred – as if it did not explicitly agree to toll all applicable limitations periods as the parties attempted to negotiate a resolution over a three-year period and even participated in mediation in April 2020 – shocks the conscience. Zeltiq is acutely (and undeniably) aware that Ms. Evangelista relied on the tolling agreements and amendments thereto in drafting and filing her Complaint and reveals itself by its footnoted reference to "unpleaded factors relating to the statute of limitations issues, such as tolling agreements between the parties." Mem. at 5, n.2.

Indeed, on December 4, 2018, the parties executed the first in a series of agreements tolling any applicable limitations period during the term of the agreement (a period of 120 days) and for sixty days after termination, or until June 2, 2019. The parties executed a second tolling agreement on June 14, 2019, tolling the running of any limitations period for ninety (90) days, or until September 12, 2019. The parties amended the second tolling agreement numerous times as they attempted to resolve this matter (even participating in mediation in April 2020), tolling the running of any limitations period until May 10, 2021. *True and correct copies of the Tolling*

Agreements and Amendments are attached to the Declaration of Daniel F. Markham, sworn to on January 18, 2022 ("Markham Decl.") as Ex. A.[1]

A. Counts I (Failure to Warn), II (Design Defect), and III (Negligence) Are Not Time-Barred.

In New York, personal injury claims alleging strict liability and negligence must be commenced within three years from the date of injury. C.P.L.R. § 214(5); *see also Victorson v. Bock Laundry Mach. Co.*, 37 N.Y.2d 395, 399-400 (1975); *Barrell v. Glen Oaks Village Owners, Inc.,* 814 N.Y.S.2d 276 (2d Dept. 2006). A cause of action accrues for purposes of C.P.L.R. § 214(5) "when all of the facts necessary to the cause of action have occurred so that the party would be entitled to obtain relief in court." *Aetna Life & Cas. Co. v. Nelson,* 67 N.Y.2d 169, 176 (1986). "Stated another way, accrual occurs when the claim becomes enforceable, *i.e.*, when all elements of the tort can be truthfully alleged in a complaint." *Snyder v. Town Insulation, Inc.*, 81 N.Y.2d 429, 432 (1993). Generally, under New York law, a cause of action "does not accrue until an injury is sustained." *Id.*

Ms. Evangelista alleges that she underwent several CoolSculpting treatments with the final rounds of treatment ending in February 2016. *ECF 17,*¶¶85-91. She is clear that it was "[f]ollowing the final round of CoolSculpting treatments" and "[w]ithin a few months" that she developed PAH. *Id.,*¶¶93,95. She alleges that she was diagnosed with PAH in or around June 2016 and makes clear that she was previously "unaware that PAH was an adverse effect associated with the use of the CoolSculpting System." *Id.,*¶¶96,94. Ms. Evangelista's strict liability and negligence causes of action accordingly did not accrue and all facts necessary to the

[1] Should this Court dismiss Counts I-X as time-barred, Ms. Evangelista respectfully requests that she be granted leave to amend pursuant to section 4.E.ii of this Court's Individual Rules of Practice in Civil Cases. *See, e.g., Bill Diodato Photography, LLC v. Avon Products, Inc.*, 2012 WL 3240428, at *4 (SDNY Aug. 7, 2012)(granting plaintiff leave to replead after refusing to consider unpleaded tolling agreement in deciding defendant's motion to dismiss).

causes of action did not occur until she developed PAH in or around June 2016. *See, e.g., Kristeller v. A.H. Robins, Inc.,* 560 F. Supp. 831, 832 (N.D.N.Y.1983)(finding plaintiff's injury occurred when she contracted pelvic inflammatory disease, not date intrauterine device was inserted, and action timely filed); *Klein v. Dow Corning Corp.,* 661 F.2d 998 (2d Cir.1981)(finding plaintiff injured on date mammary implants burst, not date of implantation). It was only at that moment that Ms. Evangelista had a colorable claim against Zeltiq and could truthfully allege all elements of her claims for strict liability and negligence. *Snyder*, 81 N.Y.2d at 432-33.

Using June 30, 2016, as the date of injury, approximately 888 days (2 years, 5 months, 5 days) ran on the statute of limitations on her strict liability and negligence claims, leaving her approximately 206 days to assert those claims at the time the parties executed the first tolling agreement on December 4, 2018. Approximately 11 more days ran on the statute of limitations between the end of the first tolling period on June 2, 2019, and the parties' execution of the second tolling agreement on June 14, 2019, leaving Ms. Evangelista approximately 194 days to assert those claims. The second tolling agreement, as amended, tolled the running of any limitations period until May 10, 2021. The statute of limitations began running again on May 11, 2021, and approximately 134 days ran on the limitations period prior to Ms. Evangelista filing her Complaint on September 21, 2021, leaving approximately 60 additional days on the statute of limitations at the time she filed her strict liability and negligence claims, and Counts I-III are not time-barred and should not be dismissed.

B. Count VI (Fraudulent Misrepresentation), VII (Fraudulent Concealment), VIII (Negligent Misrepresentation), and IX (Fraud and Deceit) Are Not Time-Barred.

Zeltiq argues that Ms. Evangelista's fraud-based claims are also subject to this three-year statute of limitations as they are incidental to her personal injury claims and, therefore, subject to

the shorter limitations period under New York law. *Corcoran v. N.Y. Power Authority*, 202 F.3d 530, 545 (2d Cir. 1999); *Fisher v. APP Pharms., LLC*, 783 F. Supp. 2d 424, 429 (S.D.N.Y. 2011). However, even under the shorter three-year period, *supra,* as approximately 60 additional days remained on the statute of limitations, as tolled, at the time Ms. Evangelista filed her fraud-based claims, Counts VI-IX are not time-barred and should not be dismissed.

C. Count X (Violation of N.Y. GBL §§ 349 and 350 Is Not Time-Barred.

Ms. Evangelista's statutory claims under GBL §§ 349 and 350 are also subject to a three-year limitations period, C.P.L.R. § 214(2), and accrual occurs when a plaintiff has been injured by a deceptive act or practice violating the statutes. *Gaidon v. Guardian Life Ins. Co. of Am.*, 96 N.Y.2d 201, 210 (2001). For the reasons *supra*, Ms. Evangelista's claims are not time-barred, and Count X should not be dismissed.

D. Counts IV (Breach of Express Warranty) and V (Breach of Implied Warranty) Are Not Time-Barred.

Under New York law, a cause of action for a breach of warranty, express or implied, is four years from the date tender of delivery is made. *Haimowitz v. Novartis Pharmaceuticals Corp.*, 148 F. Supp. 3d 327, 333 (2015)(citing N.Y.U.C.C. 2-275). "[W]here a breach of warranty claim is asserted against a drug manufacturer, the statute of limitation generally accrues at the time of the latest sale of the allegedly defective drug." *Id.*

Zeltiq's analysis of the timeliness of Ms. Evangelista's breach of warranty claims is flawed. The Amended Complaint plainly alleges that the CoolSculpting System device "is specifically programmed to function only with the use of consumable cards, or 'cycles,' that a provider must purchase in advance from Zeltiq." *ECF 17*,¶27. "A cycle is an authorization to perform one procedure to one specific area on the body; [providers] can only perform a treatment if they have purchased a cycle." *Id.*,¶28. Ms. Evangelista underwent several CoolSculpting

treatments with the final rounds of treatment ending in February 2016. *Id.,*¶¶85-91. The Amended Complaint is clear that it was "[f]ollowing the final round of CoolSculpting treatments" and "[w]ithin a few months" that Ms. Evangelista developed PAH." *Id.* ¶93,95-96. As Ms. Evangelista last underwent CoolSculpting in February 2016, it is the "cycles" purchased for use on her in those treatments that are relevant to the running of the statute of limitations on her warranty claims, and not the sale of the CoolSculpting System device itself. Because the limitations period did not begin to run until in or around February 2016, the statute of limitations, as tolled, does not run on the breach of warranty claims until in or around June 2022 and Counts IV-V not time-barred and should not be dismissed.

III. Ms. Evangelista Pleads Factual Allegations Sufficient to State a Claim for Strict-Liability – Failure to Warn

A cause of action lies in strict products liability under New York law where a manufacturer places a product on the market with a defect. *Amatulli v. Delhi Const. Corp.,* 77 N.Y.2d 525, 532 (1991). To prevail on a claim, a plaintiff need only show that the product is defective and the defect was a substantial factor in causing plaintiff's injury. *DiBartolo v. Abbott Laboratories*, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012). In New York, a product defect may be "a mistake in manufacturing, an improper design or the inadequacy or absence of warnings for the use of the product." *Amatulli,* 77 N.Y.2d at 532*;see also In re N.Y. City Asbestos Litig.,* 27 N.Y.3d 765, 787 (2016).

Ms. Evangelista asserts a strict liability claim against Zeltiq for, *inter alia*, failing to adequately warn of the serious risk of PAH following use of (and solely attributable to) the CoolSculpting System, including any information beyond denoting it "rare", accurately describing its disfiguring effect, explaining invasive liposuction surgery is the *only* option to resolve PAH, or warning PAH is permanent, does not resolve on its own and often recurs even

after surgery. *ECF 17,¶¶69-70,76-77.* These allegations place the adequacy of Zeltiq's warnings squarely at issue in this action, barring dismissal of the failure to warn claim – and application of the learned intermediary doctrine – at this time.

A. Zeltiq cannot demonstrate its warning is adequate as a matter of law.

Under New York law, "a plaintiff may assert that a product is defective because the manufacturer failed to provide adequate warnings regarding the risks and dangers associated with the use, or foreseeable misuse, of its product." *Oden v. Boston Scientific Corporation,* 330 F. Supp. 3d 877, 892 (E.D.N.Y. 2018). In bringing a failure to warn claim against a manufacturer under New York law, "[a] plaintiff must demonstrate [1] that the warning was inadequate and [2] that the failure to adequately warn…was a proximate cause of…her injuries." *DiBartolo,* 914 F. Supp. 2d at 612; *Figueroa v. Boston Scientific Corp.,* 254 F. Supp. 2d. 361, 369-70 (S.D.N.Y. 2003).

Ms. Evangelista alleges that Zeltiq, as manufacturer, had a duty to warn of known health risks and adverse effects associated with use of the CoolSculpting System, and failed to provide adequate warnings about the risk of PAH following use of the CoolSculpting System. *ECF 17, ¶¶141-42*. She specifically alleges that Zeltiq (1) had information regarding the diagnosis, treatment, and occurrence rate, which it did not disclose; (2) was inaccurate in content and ambiguous in its manner of expression; (3) purposely used the words "rare side effect" to imply that PAH is extremely unlikely to occur; (4) did not adequately inform providers or consumers about PAH, which is unfamiliar to the medical community, only associated with use of its CoolSculpting device, and about which it had superior knowledge; (5) did not provide the requisite specificity about PAH necessary to understand the true risks associated with using the CoolSculpting device; (6) did not warn that PAH is permanent; (7) did not use concrete terms like "deformity" or "disfigurement" to describe PAH; and (8) failed to warn that PAH *requires*

invasive surgery to correct, that multiple surgeries may be necessary to remove PAH, and that PAH often recurs even after surgery and can be irreversible. *Id.,¶¶140,142.* She also alleges that Zeltiq knew the risk of PAH associated with CoolSculpting, and the liability it faced as a result, but purposely downplayed and deemphasized the risk. *Id.,¶¶36-46*.

Nevertheless, Zeltiq asks this Court to dismiss Ms. Evangelista's claim based on a single, nondescript reference in an unspecified user manual that Zeltiq fails to establish it even provided to Dr. Grossman: "Paradoxical Hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required." In *DiBartolo v. Abbott Laboratories*, this District refused to dismiss a plaintiff's failure to warn claim and stated that "[i]n determining whether a warning is adequate as a matter of law, New York courts 'evaluate the [warning]'s language for its accuracy, clarity and relative consistency.' A warning is accurate if it is 'correct, fully descriptive and complete, and...convey[s] updated information as to all of the…known side effects.' A warning is clear if it employs language that is 'direct, unequivocal and sufficiently forceful to convey the risk.'" *DiBartolo,* 914 F. Supp. 2d at 612 (internal citations omitted); *see also Figueroa,* 254 F. Supp. 2d. at 369-70 (finding "the location and conspicuousness of the warning and the method in which the warning is communicated to the ultimate user" among the important considerations in determining the adequacy of warnings).

DiBartolo held: "[A] warning does not adequately warn of a side effect simply by stating that the side effect may result from use…. Rather, a warning's adequacy depends on the specific manner in which the warning advises physicians of the risk that the side effect will materialize." *Id.* The court continued: "In the context of a motion under Rule 12(b)(6), the important point is that a failure-to-warn claim will not be dismissed if the complaint sufficiently alleges that the

manufacturer, although it warned of the side effect suffered by the plaintiff, failed to warn of the side effect adequately." *Id.* at 613.

Zeltiq's lone reference to PAH, *supra*, hardly constitutes an adequate warning under *DiBartolo*, which rejected a similar "explicit warning," aptly noting that "a court deciding a failure-to-warn claim under New York law must consider not merely the existence of a relevant warning, but also the qualitative adequacy of that warning." *Id.; see also Martin v. Hacker,* 83 N.Y.2d 1, 11 (1993)(holding warning must provide sufficient information to that class of prescribing physicians "who may be expected to have the least knowledge and experience with the" product). Nor does the Grossman Consent demonstrate or evidence that Ms. Evangelista's doctor was "plainly aware" of the risk of PAH, and thus discharged Zeltiq of its duty to warn. In fact, the Grossman Consent nowhere mentions PAH and in fact downplays any such risk, vaguely stating "It is unlikely but there is a small possibility of fat growing instead of going away. There are a very small number of reports of [this] but [it] may require surgical intervention." In short, the Grossman Consent does nothing to refute Ms. Evangelista's allegations or demonstrate Zeltiq's warning adequate as a matter of law.[2] Indeed, Ms. Evangelista's factual allegations call into question the very adequacy of Zeltiq's warning in the CoolSculpting user manual (or otherwise) and thus sufficiently state a strict liability claim for failure to warn. This Court should therefore deny Zeltiq's motion to dismiss Counts I and III-X on this basis.

[2] Ms. Evangelista nowhere contends that Zeltiq is required to provide a specific numerical frequency rate of PAH to satisfy its duty to warn, but plainly alleges that Zeltiq "received thousands of reports of consumers, like Ms. Evangelista, developing PAH after treatment a[t] the time Ms. Evangelista underwent CoolSculpting," "had information regarding the diagnosis, treatment, and occurrence rate, which it did not disclose," and "purposely used the words 'rare side effect' to imply that PAH is extremely unlikely to occur." *ECF 17, ¶140-42.*

B. Zeltiq cannot shield itself from liability under the learned intermediary doctrine.

Having failed to establish its warnings adequate as a matter of New York law, Zeltiq provides this Court no grounds to dismiss Ms. Evangelista's strict liability claim, and its reliance on the learned intermediary as a basis to dismiss Counts I and III-X is misplaced. The learned intermediary doctrine is not an absolute defense, and Zeltiq cannot use it to shield itself from liability at this stage of the litigation.

1. Zeltiq has not established that the learned intermediary doctrine applies as a matter of law.

In *Bukowski v. CooperVision Inc.*, 592 N.Y.S.2d 807, 809 (3d Dept. 1993), the New York Appellate Division observed that the learned intermediary doctrine "evolved in the field of prescription drugs" and was extended to apply to certain medical devices, but declined extending the doctrine to an action against a contact lens manufacturer because it was unable to ascertain, *inter alia*, the nature of the relationship between plaintiff and the optometrist (as learned intermediary) and the role each played in plaintiff's decision to wear and selection of extended wear contact lenses manufactured by defendant. *Id.* The court ruled it could not, on the facts before it, determine whether the learned intermediary doctrine was applicable and therefore refused to reverse the trial court's denial of summary judgment based on the doctrine. The court further noted that "the informed intermediary doctrine, to be applicable, presupposes that the medical professional has been sufficiently warned of the risks of the product so that she or he may assess those risks in relation to the patient's needs" and, since it previously determined that the sufficiency of the warnings was an issue to be determined at trial, even if the court were to extend the doctrine to the case before it (which it did not), questions regarding the sufficiency of the warnings precluded a finding that defendant manufacturer was absolved of liability as a matter of law. *Id.*

Like *Bukowski*, the relationship between Ms. Evangelista and her dermatologist, Dr. Grossman, and the role each played in Ms. Evangelista choosing and electing to undergo CoolSculpting is equally at issue here. Moreover, since the adequacy of Zeltiq's warnings is at the very heart of this matter, even if the Court were to find the learned intermediary doctrine is applicable, Zeltiq cannot be absolved of all liability at this stage of the litigation on that basis alone.

Furthermore, CoolSculpting is an elective, cosmetic procedure and, unlike other more traditional prescription medical devices, the CoolSculpting System does not require a physician to administer it (Zeltiq even offers an educational program, the CoolSculpting University and CoolSculpting Masters Course, to non-medical professionals), *ECF 17,¶¶19-20,* demonstrating that the CoolSculpting System is not akin to those medical devices where the treating physician is required to administer, implant, or insert the medical device making the intervening, individualized medical judgment for his or her patient that is the underpinning of the learned intermediary doctrine. *See, e.g., Fane v. Zimmer*, 927 F.2d 124 (2d Cir. 1991)(interpreting New York law)("fixation system was available only upon supervision of a physician"); *Sita v. Danek Medical, Inc.*, 43 F. Supp. 2d 245 (E.D.N.Y. 2006)("the TSRH System is a medical device that can only be implanted by a physician"). In short, Zeltiq cannot avail itself of the learned intermediary doctrine when its CoolSculpting product does not require a "learned intermediary" to administer it.

2. Zeltiq's "targeted and strategic" direct-to-consumer advertising undercuts the purpose of the learned intermediary doctrine, rendering it inapplicable.

Importantly, none of the cases cited in *Bukowski* as applying the learned intermediary doctrine to medical devices under New York law involved a similar elective, cosmetic procedure where the manufacturer (like Zeltiq) engaged in aggressive direct-to-consumer advertising with

the stated purpose to "build[] awareness in the marketplace by having consumers (a) go to existing local practices and request treatment and drive consumable revenue, or (b) go to their local physician who does not yet have consumable services, create the desire and drive system revenue." *ECF 17,¶¶49-55*. Indeed, the strategy behind Zeltiq's direct-to-consumer campaign was not simple advertising but a strategic effort to drive revenue by injecting itself into the doctor-patient relationship and interrupting the doctor's intervening, individualized medical judgment that is at the core of the learned intermediary doctrine. Even *DiBartolo*, upon which Zeltiq relies for the proposition that New York does not recognize an exception to the learned intermediary doctrine for direct-to-consumer advertising, did not involve mass consumer marketing of this kind.

The New Jersey Supreme Court's analysis in *Perez v. Wyeth Labs*, 734 A.2d 1245 (N.J. 1999) is instructive. There, the New Jersey Supreme Court held that the learned intermediary doctrine is inapplicable when prescription drugs are directly marketed to consumers, finding direct-to-consumer advertising "alters the calculus of the learned intermediary doctrine" and holding the traditional concept of the doctor-patient relationship does not apply where manufacturers direct its advertising efforts at consumers not providers. *Id.* at 1254-55. The court stated that the justifications for applying the learned intermediary doctrine – complexity of product information, doctor's superior capability to communicate complex information, manufacturers' inability to communicate personally with individual patients, and judicial reluctance to intrude upon doctor-patient relations – are eroded when manufacturers communicate directly with consumers. *Id.* at 1255. The court held that the very fact that a manufacturer chooses to communicate directly with consumers, rather than doctors, invalidates the notion that a doctor, not a patient, decides whether a product should be used. *Id.* at 1256. The

court found that direct-to-consumer advertising undermines the doctor-patient relationship even when it encourages consumers to consult first with a physician. *Id.* at 1262. This is especially true where, as here, a manufacturer (Zeltiq) uses its direct-to-consumer advertising to drive consumer revenue in existing markets and create markets where none yet exist. *ECF 17,¶¶49-55.*

Ms. Evangelista thus pleads facts that, if proven, not only demonstrate that Zeltiq failed to adequately warn of the risk of PAH and magnitude of resulting injury, but also show that Zeltiq purposely interrupted and injected itself into the sacrosanct doctor-patient relationship by communicating with and engaging consumers directly, invalidating the notion that a provider, not patient, should make CoolSculpting treatment decisions and undercutting the very principles that justify application of the learned intermediary doctrine to traditional medical devices. In fact, Zeltiq even encouraged patients to make their own decisions regarding what treatment they want/need and, rather than heed a doctor's recommendation, "accept no substitutes for CoolSculpting." *Id., ¶¶25,52.* For these reasons, Zeltiq should not be permitted to exploit the learned intermediary doctrine in this circumstance and shield itself from liability on Ms. Evangelista's causes of action at this early stage of litigation.[3]

IV. Ms. Evangelista Pleads Factual Allegations Sufficient to State a Claim for Breach of Express Warranty.

An express warranty is "'[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods' or 'any description of the goods' and is 'part of the basis of the bargain.'" *Williamson v. Stryker Corp.,* 2013 WL 3833081, at *8 (S.D.N.Y. July 23, 2013)(quoting N.Y. U.C.C. § 2–313); *see also Goldemberg v. Johnson & Johnson Consumer Companies, Inc*., 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014)(denying motion to dismiss breach of

[3] Ms. Evangelista does not ask the Court to impose any state law duty to warn but to recognize those facts that differentiate and distinguish the CoolSculpting System from traditional medical devices and application of the learned intermediary doctrine to same. Zeltiq's preemption argument is therefore superfluous and of no consequence here.

warranty claim). "Affirmations of fact regarding the safety of a product are actionable on a claim for breach of express warranty." *Williamson*, 2013 WL 3833081, at *8.

In *Williamson v. Stryker*, this District held statements that a medical device was safe and effective – made directly by defendant's employees and on its website – were sufficient to state a claim for breach of express warranty. *Id.* The court stated that "a patient's primary concern…involving the use of a medical device is the safety of the product, and it is entirely reasonable that patients would rely upon such statements in deciding to go forward with surgery." *Id.* The district court held that, in the context of medical devices, "statements about safety are…not appropriately characterized as 'merely general statements'…that a product is generally of good or excellent quality" but "make a specific claim or promise about the potential consequences of using [the] product - that it will not be harmful or injurious - rendering such statements more specific than an assertion that a product is simply 'good.'" *Id.* at *10. *Williamson* ruled that "[t]he definition of what constitutes an express warranty is broad…and is not limited to specific kinds of statements about a product, or to specific characteristics of the product." *Id.*

While Zeltiq cites *Krulewich v. Covidien, LP*, 498 F. Supp. 3d 566 (S.D.N.Y. 2020), for the contrary proposition, the *Krulewich* plaintiffs, unlike here, made only generic, indefinite statements about the subject products and made no plausible allegations of reliance. *Id.* at 579. By contrast, Ms. Evangelista alleges that Zeltiq not only expressly warranted the CoolSculpting System as safe and effective but touted CoolSculpting as a non-invasive alternative to liposuction surgery for contouring small areas of the body and removing stubborn fat, while omitting any information about PAH risks. *ECF 17, ¶¶24,35,47-48,57-60,69,214-16,220.*

She alleges that she was promised a more contoured appearance, but the targeted fat cells actually increased in number and size and formed hard, bulging masses under her skin. *Id.,¶¶15,72,75,218.* She alleges that she was promised "No Surgery. No Downtime. Unmistakable results," but was forced to undergo multiple, costly, and painful invasive liposuction surgeries instead. *Id.,¶¶24,35,214,219*. She specifically identifies direct-to-consumer ad campaigns in or around 2014 and 2015 where Zeltiq specifically represented that "CoolSculpting technology safely delivers precisely controlled cooling to gently and effectively target the fat cells underneath the skin while leaving the skin itself unaffected" and "the results are long-term." *Id.,¶¶57,223*. She alleges that she learned about CoolSculpting, in part, from Zeltiq's direct-to-consumer advertising, promotional materials, website and social media. *Id.,¶68*, that she consulted those materials and underwent treatment based on Zeltiq's representations of safety and effectiveness, *Id.,¶¶53,72-73,75*, and that none of those materials mentioned the risk of PAH, accurately described its disfiguring effect, explained liposuction surgery is the *only* option to resolve PAH, or indicated PAH is permanent and often recurs after surgery. *Id.,¶¶69-70,76-77*. She alleges that she relied on these express warranties to her physical and economic detriment, *Id.,¶¶69-70,217,* developed PAH and suffered severe and permanent physical injuries and disfigurement as a direct result of using the CoolSculpting System. *Id.,¶¶115-30,225-29.*

And, while Zeltiq attempts to call into question Ms. Evangelista's alleged reliance, *Krulewich* makes clear: "The reliance element requires 'no more than reliance on the express warranty as being a part of the bargain between the parties.'" 498 F. Supp. 3d at 578 (quoting *CBS Inc. v. Ziff-Davis Pub. Co.*, 75 N.Y.2d 496, 453 (1990)). Ms. Evangelista's allegations, *supra*, indeed set forth facts beyond a mere legal conclusion of reliance, demonstrating the

"when, where, and how" she came to rely on Zeltiq's express warranties, *supra,* which were critical to her choosing CoolSculpting, distinguishing this action from *Krulewich* and like cases.

Furthermore, the Grossman Consent that Ms. Evangelista executed with Dr. Grossman is inapposite. By executing the Grossman Consent, Ms. Evangelista did nothing more than "request and authorize Grossman Dermatology…to perform Zeltiq-CoolSculpting Treatment." She did not release Zeltiq from liability or disclaim any claims she might have against it. *Id.* Indeed, her allegations make clear that the Grossman Consent did nothing to inform her of the risk and severity of PAH associated with (and solely attributable to) use of the CoolSculpting System. *ECF 17,¶82.* In fact, it made no mention of PAH and downplayed any potential side effects. *Id.,¶¶83-84.* Ms. Evangelista makes no admission that she was informed of, understood or acknowledged the risk of PAH. Nor does she "affirmatively disclaim[] any "guaranties [sic] or warranties of any kind, either express or implied." Also, Zeltiq is not a party to the Grossman Consent and the "guaranties or warranties" that it references have no bearing on Ms. Evangelista's claim against it for breach of express warranty.

Zeltiq attempts to refute Ms. Evangelista's allegation of breach by reference to the FDA Special Controls document, but that document in no way establishes CoolSculpting as safe and effective as a matter of law. Rather, it lays out the Special Controls that Zeltiq was to comply with in accordance with its 510(k) premarket notification. The document itself does not establish the CoolSculpting System as safe and effective or negate the sufficiency of Ms. Evangelista's allegations of breach. *Id.,¶¶36-41,224*. Moreover, Zeltiq's warranties of safety and effectiveness, *supra,* do not make up the whole of Ms. Evangelista's breach of express warranty claim, and Zeltiq does not contest Ms. Evangelista's allegations of breach as to the remaining alleged warranties, *supra.*

In short, Ms. Evangelista identifies a number of affirmations and promises by Zeltiq, the natural effect of which was to induce Ms. Evangelista, her providers, and consumers like her, to purchase CoolSculpting, and alleges when, where, and how she came to rely on those warranties in electing, purchasing, and undergoing treatment using the CoolSculpting System. Ms. Evangelista therefore sufficiently states a claim for breach of express warranty and this Court should not dismiss Count IV of the Amended Complaint.

V. Ms. Evangelista Pleads Factual Allegations Sufficient to State a Claim for Fraud.

Zeltiq moves to dismiss Ms. Evangelista's fraud-based claims (Counts VI-IX) on the grounds that she does not plead with particularity the fraudulent statements on which she bases her claims and the manner in which she and her doctor relied on same. Fed. R. Civ. P. 9(b) "requires particularity when pleading fraud…, while allowing "[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally." *Marshall v. I-Flow, LLC,* 2012 WL 3241237, at *4 (N.D.N.Y. Aug. 7, 2012). "To meet this requirement, the Complaint must: (1) specify the statement that Plaintiff contends are fraudulent; (2) identify the speaker; (3) state where and when the statement was made; and (4) explain why the statements were fraudulent." *Id.* Accepting the allegations in the Amended Complaint as true and drawing all reasonable inferences in favor of Ms. Evangelista as this Court must on a motion to dismiss, it is clear that the allegations in the Amended Complaint meet the heightened pleading requirements of Rule 9(b).

Ms. Evangelista identifies the following statements as fraudulent: (1) statements in Zeltiq's *Fear No Mirror* direct-to-consumer campaign in or around 2014 and 2015 that, *inter alia*, "CoolSculpting technology safely delivers precisely controlled cooling to gently and effectively target the fat cells underneath the skin while leaving the skin itself unaffected," *ECF*

17,¶¶57,248-49,301-03; (2) statements in Zeltiq's direct-to-consumer television, video, and website ads in or around 2015 representing CoolSculpting as safe and effective and intentionally omitting and/or minimizing the risk of PAH, *Id.,¶¶59,250,304*; (3) statements to providers in Zeltiq's promotional brochure *Preparing Your Practice for CoolSculpting* that, *inter alia*, "CoolSculpting is…proven safe. Some patients may experience temporary pain or discomfort" without mention of PAH, *Id.,¶22*; (4) statements in Zeltiq's promotional brochure for providers *Reaching Your CoolSculpting Patient Segments* that, *inter alia*, "CoolSculpting procedure eliminates fat cells safely and simply without surgery or downtime" without detailing the risk of PAH, *Id.,¶¶24,247*; (5) statements in Zeltiq's CoolSculpting Consumer FAQ that "there have been no long term effects of treatment," *Id.,¶25*; and (6) the intentional omission and and/or concealment of material information in consumer and provider advertising, marketing, and promotional materials about the risk of developing PAH after CoolSculpting, that PAH is permanent and disfiguring, that corrective liposuction surgery is the only treatment for PAH, and that PAH often recurs even after surgery, *Id., ¶¶48,303,312*.

Ms. Evangelista identifies the speaker of the fraudulent statements as Zeltiq, through its agents and employees, "which is sufficient where the defendant is a corporation, the corporation is alleged to have made the fraudulent statements, and the corporation is in the best position to know who the actual speakers were." *Marshall,* 2012 WL 3241237, at *4. And Ms. Evangelista alleges that Zeltiq knew that its CoolSculpting System device caused PAH; that PAH is solely attributable to CoolSculpting; that the pathogenesis of PAH is unknown; that, as a result, medical providers are generally unfamiliar with PAH and would therefore rely on Zeltiq's representations of safety and effectiveness; that PAH is permanent and disfiguring; that PAH requires invasive, liposuction surgery to correct; and that PAH often recurs even after surgery. *ECF 17,¶¶36-39*.

Ms. Evangelista alleges that ZELTIQ knew the actual risk of PAH associated with use of its CoolSculpting System device but downplayed the risk and, in some instances, intentionally omitted and/or concealed material information about the risk of PAH to drive consumer revenue, *Id.,¶¶40-48,253,258,268,271,286*, and indeed even demonstrates that Zeltiq knew the risk of PAH, its exposure, and the liability it faced as early as 2012 citing Zeltiq's 2012 10-K filing where Zeltiq reported this risk to the SEC despite omitting same from contemporaneous advertising, marketing and promotional materials. *Id.,¶41-46.*

These allegations demonstrate how Zeltiq's statements of safety and effectiveness, *supra*, are false and why Zeltiq omitted material information and intentionally concealed the risk of PAH in or around Ms. Evangelista's treatment, namely because it knew (and reported to the SEC) that CoolSculpting poses a serious risk, PAH, permanently disfiguring consumers, requiring invasive surgical intervention, and exposing Zeltiq to significant liability. Accordingly, Ms. Evangelista's allegations more than satisfy the particularity requirements of Rule 9(b) and clearly identify the who, what, when, and where of the alleged fraud. *See, e.g., Marshall,* 2012 WL 3241237, at *4.

Ms. Evangelista does not merely plead the contents of random promotional materials as Zeltiq contends but identifies specific fraudulent statements and material omissions by Zeltiq made to the public and providers, including Ms. Evangelista and her physician, in its advertising, marketing, and promotional materials in and around the time that Ms. Evangelista and her physician selected CoolSculpting and Ms. Evangelista underwent treatment. Ms. Evangelista specifically alleges that she learned about CoolSculpting, in part, from Zeltiq's direct-to-consumer advertising, promotional materials, website and social media. *ECF 17,¶68*; that she consulted those materials and elected to undergo and purchase treatment based on Zeltiq's

representations in those materials, *Id.,*¶¶*53,72-73,75*; and that none of those materials mentioned the risk of PAH. *Id.,*¶¶*69-70,76-77*.

She specifically alleges: (1) "Ms. Evangelista and her provider relied on ZELTIQ's representations that the CoolSculpting System was safe and effective – a quick and easy alternative to liposuction with minimal risk that required no surgery or downtime – and Ms. Evangelista purchased seven CoolSculpting treatments to achieve the promise of a more-contoured appearance," *Id.,*¶¶*52*,285; (2) "At the time she used Zeltiq's CoolSculpting System, Ms. Evangelista and her provider were unaware of the falsity of ZELTIQ's representations and reasonably believed them to be true, *Id.,*¶¶*254,287*; (3) ZELTIQ utilized a "targeted and strategic" direct-to-consumer campaign to advertise, market, and promote its CoolSculpting System directly to Ms. Evangelista and others like her, *Id.,*¶*314*; (4) Ms. Evangelista and her provider reasonably relied on ZELTIQ's false and misleading representations regarding the safety and efficacy of CoolSculpting, *Id.,*¶*315*; and (5) Ms. Evangelista and her provider believed ZELTIQ's representations to be true at the time they were made and relied upon those representations and ZELTIQ's superior knowledge in choosing to use the CoolSculpting System and was thereby induced to purchase, use, and rely on ZELTIQ's CoolSculpting System, *Id.,*¶*316*.

The Amended Complaint is not "devoid of any assertion of reliance," *Morrison v. Hoffman-La Roche*, 2016 WL 5678546, at *9 (E.D.N.Y. Sept. 29, 2016), or lack details regarding whether and how Ms. Evangelista and/or her provider received and came to rely on Zeltiq's fraudulent statements, *Cosh v. Atrium*, 2020 WL 583826, at *5 (S.D.N.Y Feb. 6, 2020), or contain nothing more than bare assertions of intent to defraud or mislead, *O'Neil v. Argon Med.*, 2020 WL 1149904, at *11 (N.D.N.Y. Feb. 13, 2020). Rather, Ms. Evangelista alleges the

very 'who, what, when, where, and how" that Rule 9(b) requires when pleading fraud. Ms. Evangelista pleads the content and context of the alleged fraudulent statements that form the basis of her fraud claims against Zeltiq as well as facts demonstrating that she consulted and relied upon those statements and that she and her physician likewise relied upon Zeltiq's representations of safety and effectiveness in choosing CoolSculpting. *See Marshall*, 2012 WL 3241237, at *4-5 ("Any false representations made to, and relied upon, by Plaintiff's physician in making the decision to use the [device] and resulting in injuries to Plaintiff (which the Complaint sufficiently alleges) give rise to a cause of action in fraud.").

Ms. Evangelista accordingly pleads her fraud-based claims with the requisite particularity required under Rule 9(b) and this Court should not dismiss Counts VI-IX of the Amended Complaint.

VI. Ms. Evangelista Pleads Factual Allegations Sufficient to State a Claim for Violation of N.Y. GBL §§ 349 and 350.

To assert a claim under N.Y. GBL §§ 349 and 350 "a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015)(quoting *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941 (2012)). The alleged conduct must be "likely to mislead a reasonable consumer acting reasonably under the circumstances." *Mahoney,* 2016 WL 3951185, at *9 (S.D.N.Y. July 20, 2016)(quoting *Cohen v. JP Morgan Chase & Co.*, 498 F.3d 111, 126 (2d Cir. 2007)). And there must be a causal "connection between the misrepresentation and some harm from, or failure of, the product." *Id.* (quoting *Orlander*, 802 F.3d at 302)). Intent to defraud and justifiable reliance by plaintiff, however, are not elements of a claim. *Oswego Laborers' Local 214 Pension Fund et al. v. Marine Midland Bank, N.A.,* 85 N.Y.2d 20, 26 (1995); *Koch v. Acker, Merrall &*

Condit Co., 18 N.Y.3d 940 (2012). The statutory claims are not subject to Rule 9(b) and need only meet the notice-pleading of Rule 8(a). *Williamson,* 2013 WL 3833081, at *13. GBL §§ 349 and 350 "apply to virtually all economic activity and their application [is] correspondingly broad." *Karlin v. IVF America, Inc.,* 93 N.Y.2d 282, 290 (1999).

Ms. Evangelista establishes all elements of a claim for violation of GBL §§ 349 and 350. She not only pleads facts sufficiently alleging that Zeltiq engaged in "consumer-oriented" conduct by, *inter alia,* aggressively marketing and advertising directly to consumers, but details Zeltiq's deceptive and misleading acts, including, but not limited to, affirmative representations that CoolSculpting be used on "individuals seeking to avoid liposuction surgery" using slogans like "SAY **NO** TO SURGERY;" "proven to be a safe and effective treatment for non-surgical fat reduction;" eliminate stubborn fat without surgery." *ECF 17,¶¶47-49.* She describes the content of various television, video, and print ads in or around Ms. Evangelista's first treatments as well as a Facebook page where Zeltiq directly communicates with consumers. *Id.,¶57-59.* She sufficiently alleges that she learned about CoolSculpting from those ads and promotional materials; that she chose CoolSculpting based on Zeltiq's representations that CoolSculpting was a safe and effective, non-invasive alternative to liposuction surgery for contouring small areas of the body; that she pursued treatment for that purpose; and that none of the materials that she consulted noted the risk of PAH, accurately described the seriousness and disfiguring effect of PAH, explained that invasive liposuction surgery is the *only* option to resolve the condition, or warned that PAH often recurs even after surgery. *Id.,¶¶53,68-77.* She alleges that she suffered physical injuries and economic loss as a result of Zeltiq's conduct, deceptive acts and false advertising. *Id.,¶¶62,96,115-32,326-30,342.*[4]

[4] Zeltiq's moving papers ignore that Ms. Evangelista's statutory claim, like each of her claims, incorporate by reference all factual allegations of the Amended Complaint. *ECF 17,¶326*.

Zeltiq nonetheless asks this Court to ignore these factual allegations – and the incontrovertible fact that Zeltiq engaged consumers directly – and even erroneously argues, under *Amos v. Biogen Idec Inc*. that Ms. Evangelista cannot state a GBL claim because the conduct alleged is not "consumer-oriented" as a matter of law. Zeltiq, however, fails to see that the Western District's application and extension of the learned intermediary doctrine to limit the reach of New York's consumer protections laws, in *Amos*, has no roots in the rule (or spirit) of New York law. *See Karlin,* 93 N.Y.2d at 290, *supra.* And this Court is not bound by its ruling. *See, e.g., Camreta v. Greene*, 563 U.S. 692, 709 n.7 (2011) ("A decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same judge in a different case.").

Indeed, New York courts have not adopted the *Amos* ruling *en masse*, and only *Wholey v. Amgen*, 56 N.Y.S.3d 16 (1st Dept. 2018), cited *Amos* in dismissing a GBL claim where plaintiff, like the *Amos* plaintiff, based its claim on a "generally alleged deceptive practice of failing to provide adequate warnings by concealing information" only – a case distinguishable from this action where Zeltiq engaged consumers directly as described *supra.*

Zeltiq's analysis also ignores two cases from this District contrary to the *Amos* court's "consumer-oriented" analysis. In *Mahoney v. Endo Health Solutions, Inc.*, the Southern District found plaintiff adequately pled a claim under GBL § 349 arising from labels and inserts on a prescription drug for children. 2016 WL 3951185, at *9. The *Mahoney* court rejected the defendants' argument that "the statements at issue were directed to doctors or pharmacists, not patients, and therefore the statements were not meant to mislead consumers." *Id*. *Mahoney* expressly rejected application of the learned intermediary doctrine to plaintiffs' statutory claim, reasoning that the doctrine is limited "to failure to warn claims." *Id.* The district court held that

"[u]nder New York law, conduct is 'consumer-oriented' when it 'ha[s] a broader impact on consumers at large," *Id.* (quoting *Crawford v. Franklin Credit Mgmt. Corp.*, 758 F.3d 473, 490 (2d Cir. 2014), and explained:

> This element thus "may be satisfied by showing that the conduct at issue potentially affects similarly situated consumers." *Sykes v. Mel S. Harris & Associates LLC*, 780 F.3d 70, 84 (2d Cir. 2015). In sum, "the injury must be to the public generally as distinguished from the plaintiff alone." *Wilson v. Nw. Mut. Ins. Co.*, 625 F.3d 54, 64-65 (2d Cir. 2010)); *see Euchner-USA, Inc. v. Hartford Cas. Ins. Co.*, 754 F.3d 136, 143 (2d Cir. 2014)("deceptive conduct aimed at the public at large" is consumer-oriented).

Id. Mahoney specifically rejected Zeltiq's argument here that the issuance of drug warnings, for purposes of GBL §§ 349 and 350, is not an act directed at consumers and therefore not a consumer-oriented act actionable under the consumer protection statutes. *Mahoney*, 2016 WL 3951185, at *9 n.11 ("The defendant's attempt to apply the learned intermediary doctrine to this suit also fails. The learned intermediary doctrine applies to failure to warn claims….").

Similarly, in *Williamson v. Stryker Corp.*, the Southern District found that defendant manufacturer's marketing of a surgically implanted knee device constituted consumer-oriented conduct under GBL §§ 349 and 350, and held:

> Plaintiffs have adequately pleaded deceptive practices and false advertising claims. Through Defendants' website and in various communications with Defendants' employees, Defendants represented that the [device] was generally "safe and effective," a "proven technology," a "significant success"…. Nowhere on the website or in conversations with Plaintiffs did Defendants address any potential risk of the device breaking.

2013 WL 383308, at *13-14. The *Williamson* court determined that "[t]he representations on the website were clearly consumer-oriented, as they were directed and available to the public at large through the Internet." *Id.* The court made clear that "[t]he standard for establishing consumer-

oriented conduct is very liberal, and where a defendant deals with a plaintiff in the same way as it would deal with any other customer, such conduct is considered 'consumer-oriented.'" *Id.*

For these reasons, Ms. Evangelista sufficiently states a statutory claim under N.Y. GBL §§ 349 and 350, and this Court should not dismiss Count X of the Amended Complaint.

CONCLUSION

WHEREFORE, Plaintiff Linda Evangelista respectfully requests that this Court deny Defendant Zeltiq Aesthetics, Inc.'s motion to dismiss the Amended Complaint in part, and grant such other and further relief as this Court deems just and proper. Should this Court grant Zeltiq's motion, Ms. Evangelista respectfully requests leave to amend the Amended Complaint pursuant to section 4.E.ii of this Court's Individual Rules of Practice in Civil Cases.

Dated: New York, New York
January 18, 2022

WROBEL MARKHAM LLP

By: Daniel F. Markham

Daniel F. Markham (DM8431)
1407 Broadway, Suite 4002
New York, New York 10018
Tel: (212) 421-8100
dmarkham@wmlawny.com
Attorneys for Plaintiff Linda Evangelista